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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,307	03/21/2001	Naoto Oku	50026/024001	2668

21559 7590 05/28/2003

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/28/2003

224

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/623,307

Applicant(s)

OKU ET AL.

Examiner

Janet L. Epps-Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 53-56 is/are allowed.
- 6) ☒ Claim(s) 26-52 and 57-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-24-03 has been entered.

Response to Amendment

Claim Rejections - 35 USC § 112

2. Claims 26-50 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended claim 26 to recite wherein said polyalkylenimine or said salt comprises..."(b) seven or more nitrogen atoms, and wherein the degree of substitution on said nitrogen atoms is $\leq 24.5\%$." As support for this amendment Applicants reference page 10, lines 2-23, and page 22, line 2. However, contrary to Applicant's assertions, the specification as filed, page 10, lines 2-23, and page 22, line 2, does not disclose generic wherein the degree of substitution on said nitrogen atoms of the polyalkylenimine is $\leq 24.5\%$. The specification as filed does disclose a polyalkylenimine having 24.5% alkylation of the nitrogen atoms. However, amended claim 26 does not limit substitution of the nitrogen atom to solely alkylation, claim 26 broadly encompasses substitution with any other suitable nitrogen substituting group, e.g.

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hydrogen. The term "Da" or Dalton does not accompany the term "300" as recited on page 10 of the specification. It is unclear what unit of measurement Applicants are referring to on page 10 of the specification. In the examples, however, Applicants describe the weight of the synthesized polyethylenimine compounds in terms of grams and moles. Moreover, it is unclear what calculations Applicants used to determine wherein a molecular weight of 300 Da , corresponds to a polyethylenimine of seven nitrogen atoms. Applicants have not accounted for the contribution of other molecules in the polyethylenimine structure.

Additionally, Applicants have amended the instant claims to recite wherein the base skeleton of the polyalkylenimine does not comprise a carbonyl group. Again, Applicant's specification does not provide adequate support for this limitation. Although the terminology "a saturated or unsaturated acyloxycarbonyl group" has been removed from the claims, formulas I , II, and III, on pages 11-12 of the specification as filed clearly encompasses polyalkylenimines comprising a carbonyl group.

Applicant's amendment to claim 26 constitutes new matter, since the specification as fails to provide proper antecedent basis for the claimed subject matter, particularly wherein the polyalkylenimines of claim 26 comprise "... (b) seven or more nitrogen atoms, and (c) a base skeleton that does not comprise a carbonyl group." See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 51-52, and 57-63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite the terms “about 600 Da” and “about 1800 Da.” However, neither specification as filed, nor the original claims provide an adequate definition for the term “about” as used in the context of these claims, such that the ordinary skilled artisan would be able to ascertain the metes and bounds of the claimed invention.

Conclusion

5. Claims 51-52, and 57-63 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.
6. Claims 53-56 are free of the prior art searched.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 703-308-8883.

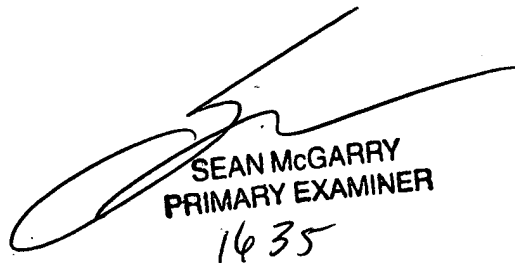
The examiner can normally be reached on M-T, Thurs-Fr, 9-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L. Epps-Ford
Examiner
Art Unit 1635

jle
May 23, 2003


SEAN MCGARRY
PRIMARY EXAMINER
1635